

Complete Summary

GUIDELINE TITLE

Medication-assisted treatment for opioid addiction in opioid treatment programs:
Drug testing as a tool.

BIBLIOGRAPHIC SOURCE(S)

Drug testing as a tool. In: Batki SL, Kauffman JF, Marion I, Parrino MW, Woody GE, Center for Substance Abuse Treatment (CSAT). Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD: Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. p. 143-59. (Treatment improvement protocol (TIP); no. 43).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Opioid addiction

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation
Management

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Psychiatry
Psychology

INTENDED USERS

Nurses
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

To provide guidelines for drug testing in medication-assisted treatment for opioid addiction (MAT)

TARGET POPULATION

Patients with an addiction to opioids who are eligible for medication assisted treatment programs

INTERVENTIONS AND PRACTICES CONSIDERED

1. Drug testing for:
 - Treatment compliance (e.g., methadone and its metabolites) (Currently, no tests for buprenorphine or levo-alpha acetyl methadol [LAAM] are commercially available.)
 - Substances of abuse (e.g., opioids, cocaine, and benzodiazepines, methamphetamine, alcohol, marijuana)
2. Types of testing
 - Urine drug testing
 - Oral-fluid drug testing
 - Blood drug testing
 - Sweat drug testing (sweat patches)
 - Hair drug testing
3. Components and methods
 - Specimen collection setting and approach
 - Direct observation of specimen collection versus other methods
 - Analytical methods used in drug testing (e.g., enzyme immunoassay, fluorescence polarization, kinetic interaction of microparticles [KIMS], colloidal metal immunoassay [CMI], radioimmunoassay, thin-layer chromatography [TLC], gas chromatography/mass spectrometry (GC/MS)
4. Development of written procedures
5. Other considerations
 - Frequency of testing
 - Laboratory selection
 - Onsite test analysis
6. Interpreting and using drug test results
 - Responding to unfavorable drug test results

- Strategies for minimizing patient falsification of test results
7. Ensuring reliability, validity, and accuracy of drug test results
- Minimizing false positive and false negative drug-testing results
 - Responding to test results
 - Making decisions about take-home medications

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of drug test results
- False positive and false negative test results

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search involved careful consideration of all relevant clinical and health services research findings, practice experience, and implementation requirements.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

After selecting a topic, Center for Substance Abuse Treatment (CSAT) invites staff from pertinent Federal agencies and national organizations to be members of a resource panel that recommends specific areas of focus as well as resources that should be considered in developing the content for the Treatment Improvement Protocols (TIP). These recommendations are communicated to a consensus panel composed of experts on the topic who have been nominated by their peers. This consensus panel participates in a series of discussions. The information and recommendations on which they reach consensus form the foundation of the TIP. The members of each consensus panel represent substance abuse treatment programs, hospitals, community health centers, counseling programs, criminal justice and child welfare agencies, and private practitioners. A panel chair (or co-chairs) ensures that the contents of the TIP mirror the results of the group's collaboration.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A large and diverse group of experts closely reviews the draft document. Once the changes recommended by these field reviewers have been incorporated, the Treatment Improvement Protocol (TIP) is prepared for publication, in print and on line.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Purposes of Drug Testing in Opioid Treatment Programs (OTPs)

Given the regional variability in factors affecting addiction, for example, differences in heroin purity and availability or in prescription opioid abuse, the consensus panel recommends that OTPs develop new measures to improve outcomes if they report an average of more than 20-percent positive drug tests for patients with at least 1 to 3 years of medication-assisted treatment for opioid addiction (MAT). Equally important, OTP drug test results should be nearly 100-percent positive for treatment medications because lower percentages could

indicate medication diversion, which requires investigation and a corrective-action plan.

Testing for Treatment Compliance

At a minimum, most specimens from patients maintained on methadone should be tested for methadone and its metabolites (testing for metabolites prevents patients from simply adding methadone to a sample), which can be done efficiently and at reasonable cost. Currently, no precise test measures buprenorphine in a patient specimen, although it can be detected in urine, blood, or hair by gas chromatography/mass spectrometry (GC/MS) and by enzyme-linked immunosorbent assay in urine. Until new, commercially available tests are developed, drug testing of patients receiving buprenorphine primarily should be to detect substances of abuse. No reagent is commercially available at reasonable cost to test any specimen type for levo-alpha acetyl methadol (LAAM), although LAAM can be detected in urine by thin-layer chromatography (TLC) and GC/MS. Therefore, the consensus panel recommends direct monitoring of patients receiving LAAM, assuming that its availability continues.

Testing for Substances of Abuse

At a minimum, OTPs should test for opioids, cocaine, and benzodiazepines and consider testing for other drugs (e.g., methamphetamine), depending on local substance use patterns. OTP administrators should decide whether to test routinely for alcohol and marijuana or only as needed. Because of the increased depressive effects of alcohol combined with an opioid such as methadone, it is important for OTPs to avoid providing opioid medication to patients who are intoxicated with alcohol. However, no standard cutoff scores for permissible alcohol levels exist across OTPs. Because urine tests for alcohol are highly variable, breath and blood tests are more useful in OTPs to determine the presence or degree of acute alcohol intoxication. Because breath tests are much simpler and faster and are less invasive than blood tests, they are the most common alcohol testing method used in OTPs.

Exhibit 9-1 in the original guideline document summarizes necessary minimum (or cutoff) concentrations for detection of some illicit and prescription drugs in urine, as well as their reliable detection times for both initial patient testing and confirmation of positive results.

Benefits and Limitations of Drug Tests

The consensus panel cautions that drug test results should not be the only means to detect substance abuse or monitor treatment compliance and that the needs of patients whose test results show no immediate problems should not be overlooked. Too often, overworked counselors and caseworkers scan drug test results to determine services, without investing time to develop the trust and concern inherent in a sound counseling relationship. Training and educating staff members about the benefits and limitations of drug tests should ameliorate this situation. Staff members should understand, for example, that certain prescribed and over-the-counter medications and foods might generate false positive and false negative results for different substances. Some drug-testing laboratories provide training about drug testing for OTP staff. Frank discussions of the issues

involved for patients and for the OTP help staff members understand the importance of using test reports appropriately.

Urine drug testing remains the most common method of drug testing in OTPs. The Substance Abuse and Mental Health Services Administration (SAMHSA) has notified OTPs that they may use oral-fluid testing to satisfy the drug-testing requirements in 42 Code of Federal Regulation (CFR), Part 8, if a program's medical director deems this method adequate. As other drug testing methods are developed and attain Federal and State approval, OTPs should consider using them as well.

Urine Drug Testing

Despite its limitations, urine drug testing is dominant in OTPs because obtaining specimens is relatively easy and testing is affordable. In addition, the technique is well studied, has been in use for a long time, and has well-established cutoff levels and other laboratory guidelines.

A patient's physical condition can affect test sensitivity and specificity. Urine testing is not feasible for patients with renal failure (e.g., those on dialysis) or other bladder control impairments. Furthermore, individuals with paruresis ("shy bladder syndrome") have a social anxiety disorder that may leave them unable to urinate under observation.

Just as some patients metabolize methadone or other treatment medications at different rates and some medications affect the metabolism of others, certain medications, for example, human immunodeficiency virus (HIV) medications, change the metabolism of addiction medications and can affect drug test results. OTP staff members should remain current on these interactions as more data become available.

Oral-Fluid Drug Testing

Oral-fluid drug testing is an alternative to urine drug testing in OTPs that is approved by SAMHSA, but only when a qualified offsite laboratory performs the specimen analysis. According to SAMHSA's interim guidance on the use of oral-fluid testing in OTPs, sent to OTPs in July 2003, offsite drug testing using oral fluid may be considered adequate for the purpose of federal regulations. The choice of drug-testing methodology is an informed medical judgment decision. It is SAMHSA's view that there is sufficient information to confirm the adequacy of oral-fluid testing in the OTP setting. The Center for Substance Abuse Treatment (CSAT) noted that OTPs still must conform to State laws and regulations in this area.

Results of oral-fluid testing generally are similar to those obtained by urine drug testing, but differences exist, and OTP staff members should understand these differences. Concentrations of some substances are lower in saliva than in urine. Some drugs remain detectable longer in urine than in saliva. Drug residue in the oral or nasal cavity was found to contaminate saliva specimens. The consensus panel recommends oral-fluid testing when drug testing must be observed because it is more respectful and less invasive and observation does not require watching

patients void. Oral-fluid collection requires no temperature strips or other devices to ensure that a specimen was just provided.

Blood Drug Testing

OTPs rarely if ever use blood testing routinely; most often, they use this method to monitor plasma methadone levels when necessary. Testing for the presence of methadone in serum, although more costly than urine testing, is the most accurate method currently available to determine whether other prescribed medications influence methadone metabolism or a patient is a rapid metabolizer. Serum testing is more accurate than other methods to address issues related to the effects of metabolism on methadone dosage.

Blood testing has limitations besides cost. Blood offers a smaller drug detection window than oral fluid or urine; most drugs are undetectable in blood after 12 hours. Trained personnel must obtain blood specimens. Concerns about blood-borne pathogens make routine blood testing impractical, and some medications and diseases affect methadone levels in plasma.

Sweat Drug Testing

Sweat patches usually are used as an adjunct to other forms of testing. They provide a longer specimen collection period than either urine or blood and may be less susceptible to tampering than urine. Sweat patches are tolerated well by patients and are considered less invasive and less potentially embarrassing.

Playing-card-sized, waterproof adhesive patches are available. Each patch is imprinted with a unique number to track its chain of custody. After a patch is worn for about 1 week, a laboratory can extract about 2 mL of sample to be tested. Compared with urine specimens, sweat yields higher proportions of parent drugs, such as cocaine, heroin, or marijuana. Drug use is assessed cumulatively, but uniform cutoff levels have not been established, and external contamination is a possibility.

Hair Drug Testing

Hair analysis provides a longer term look at drug use than other methods because hair retains drugs longer--for example, weeks or months, compared with the 2 or 3 days that cocaine or heroin is detectable in urine. Collecting hair specimens also is less invasive than urine or blood sampling. However, drawbacks include expense, possible ethnic bias, and environmental contamination. Studies of hair analysis have been hampered by poor design, small specimen size, and lack of confirmation. More research is needed.

Drug-Testing Components and Methods

Methods and uses of drug tests vary widely among OTPs. Improvements in standards and technology have made a variety of testing and analytical alternatives available. Drug testing is a multistep process that starts with specimen collection. Specimens are analyzed by one of numerous techniques. The results are recorded and interpreted. When an initial test analysis is positive for a

substance of abuse or unexpectedly negative for a treatment medication such as methadone, providers should discuss the results with the patient as soon as possible. If the patient insists that a result is inaccurate, an OTP should recheck the existing report via confirmatory analysis or a retest if the laboratory still has the specimen in question. Preferably, a different analytical method with higher sensitivity is used for confirmation or retesting. A confirmed analysis should be viewed as only one basis for modifying a patient's treatment plan.

The consensus panel recommends that programs incorporate Federal and State regulatory requirements and their own treatment needs into written policies and procedures for drug testing and integrate these policies and procedures into treatment planning and practices. OTP administrators should consider the factors discussed below in establishing and maintaining drug-testing procedures that ensure the integrity and utility of results, as well as compliance with regulations.

Specimen Collection

Setting and Approach

The consensus panel emphasizes that specimen collection and testing should be performed in a therapeutic, humane environment and results should be used to help guide patient care, modify treatment plans, and confirm clinical impressions. Specimen collection methods should protect patients' dignity and privacy while minimizing opportunities for falsification. The bathrooms used for urine collection should be cleaned frequently and supplied with soap and other toilet articles. Collection procedures should be in writing (see "Development of Written Procedures" below). Patients should be informed during admission and early treatment about how drug-testing specimens are collected and patients' responsibility to provide specimens when asked. Patients should receive a copy of OTP policies on and procedures for drug testing, including whether and when direct observation is indicated.

Most OTPs assign a staff member to greet patients and determine whether a urine specimen is required before patients can receive medication. This determination may be based on staff judgment or a random list generated by computer or by OTP managers. In most cases, urine specimens should be obtained randomly based on patients' OTP visit schedules.

When indicated, a patient is sent to the bathroom to provide a urine specimen in a labeled container. Most programs monitor the bathroom to ensure that only one patient uses it at a time and that patients leave parcels outside the bathroom. The person receiving the urine specimen checks the container to determine whether it is a valid specimen. The specimen then is packaged and sent to a laboratory for testing.

To ensure patient confidentiality, programs should store specimens and related documents and material so that only authorized personnel can access and read them. Handling specimens also raises questions about staff safety and the reliability of the chain of custody for samples. Universal safety precautions for handling urine specimens should be followed; for example, staff members collecting specimens need to wear gloves.

Direct Observation Versus Other Methods

Collecting urine specimens, especially when collection is supervised, can be embarrassing for both subjects and supervisors and raises concerns about patients' privacy rights. Some patients and treatment providers perceive direct observation of urination as a violation of trust and respect. In addition, patients with paruresis should not be penalized; instead, treatment providers should consider unobserved urine testing, oral-fluid testing, or another drug-testing method.

The consensus panel recommends that OTP staff members use their clinical judgment regarding the need for direct observation of urine collection. Temperature strips, adulterant checks, and other methods should be used when possible to ensure test validity. Many OTPs do use direct observation, but some use one-way mirrors and even video cameras to ensure reliable sample collection.

OTPs that use observed collection have many options, including random observation, observation to ensure treatment compliance before a schedule change, or observation because of suspected drug use. Some OTPs use direct observation only during initial stabilization. Oral-fluid testing is another option. Each OTP should decide whether, when, and how it uses direct observation in specimen collection and should include guidance for direct observation in its written policies and procedures. Some States mandate urine drug testing and direct observation of specimen collection. For programs that elect unobserved collection, other effective options for sample validation exist, such as temperature strips and ambient-temperature "guns" (see below).

Analytical Methods Used in Drug Testing

Knowledge gained from testing enhances the treatment process and ameliorates some regulatory concerns and issues facing OTPs. However, it is important for practitioners and State and Federal regulators to understand the limits of the drug testing and analytical methods used in most OTPs.

Because of the volume and cost of urine testing, most OTPs use thin-layer chromatography (TLC) or enzyme immunoassay (EIA) to analyze test specimens. The Enzyme Multiplied Immunoassay Technique (EMIT) is the EIA method used most often in this country because its costs are lower, it allows for short analysis time, it can be automated for large-scale samples, and it can be used on site by small programs.

Immunoassays use antibodies with specific surface sites to which drugs or metabolites bind. For urine drug testing, either of two immunoassay types--radioimmunoassay (RIA) or EIA--can be used. RIA uses radioactive markers and requires an incubation period and centrifugation of the sample. EIA uses an enzyme as its marker. Currently, no commercially available EIA tests exist for LAAM, buprenorphine, or the buprenorphine-naloxone combination tablet.

EIA permits detection of extremely small quantities of substances but lacks specificity to determine which drug in a class is present. For example, EIA can detect opioids but cannot distinguish between morphine (the metabolite of heroin excreted in urine), codeine, and other opioids, including those from poppy seeds

used in baked goods. EIA does not distinguish oxycodone (e.g., Percodan®, OxyContin®). In areas where these drugs are abused, OTPs should take additional steps and use other methods to test for oxycodone. See Exhibit 9-2 in the original guideline document for descriptions of several widely available immunoassays.

Chromatographic analyses use flows of liquid or gas to separate molecules and isolate any drugs or drug metabolites in specimens. TLC, one of the oldest of these methods, is inexpensive but less accurate than EIA, and its accuracy depends on the skill of the laboratory technician. TLC can distinguish between drugs in a class (a limitation of EIA), but it also can produce false negative reports because it requires relatively large amounts of drugs in specimens before these drugs can be detected. Programs working with laboratories that use TLC should be aware that low doses of addiction treatment medication occasionally yield negative reports. When methadone is used in treatment, periodic assays for its primary metabolite, EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine), are advised. Unlike methadone, EDDP is pH independent when excreted, so the absence of EDDP from urine may be a more accurate sign of tampering, substitution, or diversion. GC/MS is a sensitive method that can be used to confirm results from EMIT or TLC.

Development of Written Procedures

Procedures for drug testing in an OTP should be described clearly in a written document such as that shown for urine specimen collection in Exhibit 9-3 of the original guideline document. Similar policies can be developed for oral-fluid testing. Each OTP should develop policies and procedures for drug testing based on its mission, service philosophy, and practices.

Other Considerations in Drug-Testing Procedures

Frequency of Testing

Given concerns about the cost and reliability of drug tests, some OTPs limit testing and others assume that results are unreliable in many cases. Decisions about how to use drug testing require thought and balance. In addition to conforming to Federal and State regulations, the frequency of testing should be appropriate for each patient and should allow for a caring and rapid response to possible relapse. Drug tests should be performed with sufficient frequency and randomness to assist in making informed decisions about take-home privileges and responses to treatment.

For patients who continue to abuse drugs or test negative for treatment medication, the consensus panel recommends that OTPs institute more frequent, random tests. Increased testing provides greater protection to patients vulnerable to relapse because only short periods pass before a therapeutic intervention can be initiated. However, as emphasized throughout this chapter, programs should avoid making treatment decisions affecting patients' lives that are based solely on drug test reports.

SAMHSA requires eight drug tests per year for patients in maintenance. In the opinion of the consensus panel, this is a minimal requirement. The actual

frequency of testing should be based on a patient's progress in treatment, and more testing should be performed earlier in treatment than later, when most patients are stabilized. Most OTPs develop policies and procedures on testing frequency that meet or exceed Federal requirements and accreditation standards to assist staff in planning treatment, assessing patient progress, and granting take-home privileges.

Some States require more frequent testing than that required by SAMHSA. Some also require that specific drug-testing methodologies or decision matrices be followed. OTPs must adhere to the more stringent of either the Federal or State regulations. In States with no specific requirements, Federal regulations are the only applicable standard, but, as previously noted, these requirements should be considered minimal and regulatory.

The consensus panel recommends at least one drug test at admission to an OTP. Onsite testing kits are available so that admission can continue while test results are pending (see "Onsite Test Analysis" below), although some States may disallow these kits. For patients in short-term detoxification, one initial drug test is required, whereas patients receiving longer term medication-assisted treatment for opioid addiction (MAT) are required to have initial and monthly random tests.

Laboratory Selection

The laboratory selected by an OTP to analyze patient specimens must comply with Health Insurance Portability and Accountability Act regulations and the Clinical Laboratory Improvement Amendments (CLIA). OTPs should understand a laboratory's analytical methods and know whether and how often the laboratory confirms positive findings, how long specimens are retained for testing, and when results are made available to OTPs. A laboratory should collaborate with an OTP regarding custody of specimens, confidentiality and reporting of results, turnaround times for results, and specimen retention for retesting. Programs also should understand a laboratory's minimum cutoff levels for determining and reporting positive results.

Onsite Test Analysis

Onsite (also known as near-patient or point-of-care) drug test analysis can provide rapid results but may have limitations such as increased cost or reduced accuracy. Some State regulations disallow onsite test analysis.

Onsite analysis of test specimens also requires that staff be trained in calibration of the testing device and interpretation of results. OTPs need ongoing quality assessment procedures. Analyses performed outside a laboratory setting require special facilities to ensure safety. Onsite specimen analysis also raises questions about the chain of custody, provision, stability, and storage of samples. However, the U.S. Department of Health and Human Services is developing guidelines for onsite analytical methods in workplace drug-testing programs, which suggests that this approach will become more common. The use of onsite specimen analysis for decision-making may subject OTPs to the requirements of CLIA—Federal guidelines for any entity doing laboratory analysis of specimens from humans—and require these OTPs to obtain approval from their State health

departments. If an OTP falls under CLIA requirements, it must register or seek a waiver to continue its own laboratory analysis of test specimens.

Interpreting and Using Drug Test Results

Test results should be documented in patient records along with appropriate justifications for subsequent treatment decisions, particularly in unusual situations such as when take-home medications are continued despite test results that are consistently positive for substances. OTPs should confirm positive results whenever possible, bearing in mind the factors that can confound results (e.g., using over-the-counter medications, eating foods containing poppy seeds).

OTP directors should ensure that results are not used to force patients out of treatment and that no treatment decisions are based on a single test result. Patients should be informed of positive results for substances of abuse or negative results for treatment medication as soon as possible and should have an opportunity to discuss these results with OTP staff. A patient who refutes test results should be taken seriously, particularly when results are inconsistent with the treatment profile and progress of that patient.

OTPs should use drug test results clinically--not punitively--for guidance, treatment planning, and dosage determination. OTPs should retest (using more sensitive analytical methods if necessary) when results indicate continuing problems; monitor carefully the chain of custody for specimens; document results, patient responses, and action plans in the case record; respond rapidly to relapse indications; and ensure that positive results for substance abuse or negative results for treatment medication trigger treatment, relapse prevention counseling, HIV counseling, and other intensified interventions. Continued use of heroin or other opioids (and possibly other substances) should generate a review of a patient's addiction medication dosages.

Responding to Unfavorable Drug Test Results

Patients who continue to abuse substances while receiving addiction treatment medication create concern among OTP staff members for their progress in treatment, negative perceptions of OTPs, and community concerns that may lead to regulatory actions by SAMHSA, accrediting bodies, or the U.S. Drug Enforcement Administration.

Most OTPs must review a significant number of unfavorable drug test results. Again, the consensus panel emphasizes that results should be used to explore different treatment interventions and treatment plans that will reduce and eliminate substance use and improve treatment compliance. Reports indicating substance abuse should signal the need for a medical review of medication dosage and for intensification of counseling and education aimed at preventing HIV and hepatitis transmission. Also, because of regulatory concern about medication diversion, reports indicating absence of treatment medication should be evaluated carefully. Because dose, pH, and urine concentration can limit detection of treatment medications, staff members should consider all these areas in conducting their medical reviews and deciding on a plan of action.

When patients deny substance use despite a positive laboratory result, a careful history of their prescribed or over-the-counter drug use should be obtained and discussed with a pathologist or chemist to determine whether these drugs might produce false positive results or otherwise confound tests. Whenever possible, a questionable test should be redone (if the specimen is available) and the result confirmed by another method. If this is impossible, confirmatory analysis should be performed for all subsequent tests. More accurate testing methods such as RIA or GC/MS can be used to verify laboratory reports. Specimens can be collected under direct observation, and a chain of custody can be maintained to assure a patient that every effort is being made to prevent errors and respond to his or her denial.

Confirmations of positive drug test results generally are conducted in a laboratory rather than at the OTP.

Patient Falsification of Test Results

Strategies to minimize sample falsification should be balanced by sound treatment ethics and the overall goals of the program--recovery and rehabilitation. Common strategies include

- Turning off hot water in bathrooms to prevent patients from heating specimens brought from elsewhere (although not feasible in States where other regulations prohibit this step)
- Using bathrooms within eyesight of staff to preclude use by more than one person at a time and feeling specimen containers for warmth as soon as received (freshly voided specimens should be near body temperature [37 degrees C])
- Using temperature and adulterant strips or collection devices that include temperature strips
- Using a temperature "gun" (infrared thermometer [visit www.coleparmer.com]) to measure the temperature of urine specimens
- Using direct observation by staff of specimen collection.

The consensus panel believes that falsification is reduced when patients understand that urine test results are not used punitively to lower doses of addiction treatment medication. Continued use of drugs requires counseling, casework, medical review, and other interventions, not punishment. In the past, some OTPs reduced medication dosages as a direct result of positive drug tests although this has proved ineffective and sets up an adversarial relationship between patients and the OTP. When it is clear that interventions for substance abuse are ineffective, moving patients to a higher level of care, rather than discharging them, is warranted.

Patients should be encouraged to discuss their substance use with OTP physicians, caseworkers, or counselors and to trust them with this information. Ideally, once trust has developed, drug test results will confirm what already has been revealed in individual or group sessions. Nevertheless, some patients fear loss of take-home privileges or remain in denial about their drug use and do not disclose their noncompliance willingly; drug test results are necessary to alert OTPs to these patients' noncompliance.

Reliability, Validity, and Accuracy of Drug Test Results

Another critical concern is the reliability of drug testing, which varies by methodology. Accuracy also depends on the choice of laboratory, use of proper equipment and methods, quality control, and adherence to high-quality standards by all involved. As in all laboratory testing, human errors, confounding results, a poorly controlled chain of custody for samples, and other problems lower test reliability.

In the opinion of the panel, urine drug testing is reliable and valid. A number of studies have examined the validity and accuracy of various urine drug-testing analytical methods. Studies generally report that urine analysis by EIA techniques is at least 70 percent as accurate as that for RIA or GC/MS.

On the basis of cost, the consensus panel believes that EIA and TLC usually are adequate analytical methods in OTP drug testing. When results are contested or confusing, confirmation analyses should be performed. For example, when EIA indicates the presence of illicit drugs but the patient denies any drug use or has progressed well in treatment, confirmatory GC/MS can be useful. Confirmatory analysis offsets the limitations of single tests.

False Positive and False Negative Drug-Testing Results

Numerous medications and substances can produce false positive results in urine drug tests.

Although EIA can produce some false positive results, TLC may be less sensitive than EIA, causing more false negative results. In addition, laboratory and clerical errors and other problems cause inaccuracies. To check for any problems, unexpected results should be discussed with the laboratory before they are conveyed to the patient.

Responses to Test Results

Staff members should discuss drug test results with patients using a therapeutic, constructive approach. For example, staff members might express concern to patients over any tests that are positive for illicit drugs and seek additional information to explain these results. If a patient receives medication from a physician outside the OTP, staff should request informed consent to contact the physician and coordinate treatment, ask the patient to bring in prescription bottles, and record these prescriptions in patient records. OTP physicians should review prescriptions to determine whether and for how long their use is appropriate, particularly when medications have abuse potential.

Ultimately, if a positive drug test represents continuing drug use or a relapse after a period of abstinence, the counselor and patient should explore strategies to eliminate future use. Medication dosage and triggers to substance use should be examined, motivation for abstinence should be explored, and the patient should be taught skills to manage triggers and cravings. If drug tests continue to be positive, the medication dosage, amount of counseling, and number of OTP visits should be evaluated and may need adjustment. Furthermore, the patient might

need the support provided by increasing counseling sessions and drug tests. These changes should be reflected in an updated treatment plan.

Medication Diversion

Since methadone treatment gained prominence in the late 1960s, concerns have existed about the diversion of medication from legitimate treatment use through theft, robbery, or patients or staff selling or giving away medication. SAMHSA-approved accrediting bodies pay particular attention to drug test results and whether an OTP appropriately monitors and follows up with patients who receive take-home medications. The accrediting bodies require all OTPs to develop and implement a diversion control plan as part of their quality assurance program and to integrate the plan into both patient and staff orientations. The diversion control plan must contain specific measures to reduce the possibility of diversion and assign specific implementation responsibility to medical and administrative staff.

Decisions About Take-Home Medication

Although drug test reports are a key factor in take-home medication decisions, OTPs should consider and document other considerations, such as employment and medical problems. Current Federal regulations outline eight criteria that the medical director of the OTP must consider when granting take-home privileges. The physician also is required to reevaluate the appropriateness of take-home medications at least every 3 months.

Sometimes privileges are revoked simply to prevent possible medication diversion, without a concomitant programmatic response to address an unfavorable drug test report. When this occurs without discussion or explanation, OTPs create barriers between themselves and patients and appear to function more as monitoring and surveillance units than as treatment programs. If patients who are receiving take-home medications have positive drug test results, OTPs should consider such steps as a review of medication dosage and an increase if indicated, revision of the patient treatment plan, or an increase in the level of care, in addition to cessation or reduction in take-home doses.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations are based on a combination of clinical experience and research-based evidence.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Monitoring of treatment compliance and ensuring patients receive appropriate care
- Drug test results help policymakers and opioid treatment program (OTP) administrators detect and monitor emerging trends in substance abuse that may signal a need to redirect resources.

POTENTIAL HARMS

False positive and false negative drug test results

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The opinions expressed herein are the views of the consensus panel members and do not necessarily reflect the official position of Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), or Department of Health and Human Services (DHHS). No official support of or endorsement by CSAT, SAMHSA, or DHHS for these opinions or for particular instruments, software, or resources described in this document is intended or should be inferred. The guidelines in this document should not be considered substitutes for individualized client care and treatment decisions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Chapter 14, Administrative Considerations, in the original guideline document, covers the challenging administrative aspects of managing and staffing the complex and dynamic environment of an opioid treatment program (OTP). Successful treatment outcomes depend on the competence, values, and attitudes of staff members. To develop and retain a stable team of treatment personnel, program administrators must recruit and hire qualified, capable, culturally sensitive individuals; offer competitive salaries and benefit packages; and provide good supervision and ongoing training. Implementing community relations and community education efforts is important for opioid treatment programs. Outreach and educational efforts can dispel misconceptions about medication-assisted treatment for opioid addiction and people in recovery. Finally, the chapter provides a framework for gathering and analyzing program performance data. Program evaluation contributes to improved treatment services by enabling administrators to base changes in services on evidence of what works. Evaluation also serves as a way to educate and influence policymakers and public and private payers.

Refer to Chapter 14 in the original guideline document for full details (see "Companion Documents" field in this summary).

IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Drug testing as a tool. In: Batki SL, Kauffman JF, Marion I, Parrino MW, Woody GE, Center for Substance Abuse Treatment (CSAT). Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD: Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. p. 143-59. (Treatment improvement protocol (TIP); no. 43).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

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GUIDELINE COMMITTEE

Treatment Improvement Protocol (TIP) Series 43 Consensus Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Steven L. Batki, MD (Chair), Professor and Director of Research, Department of Psychiatry, SUNY Upstate Medical University, Syracuse, New York; Janice F. Kauffman, RN, MPH, LADC, CAS (Co-Chair), Vice President, Addiction Treatment Services, North Charles Foundation, Inc., Cambridge, Massachusetts; Director, Addiction Psychiatry Service, Department of Psychiatry, Brigham and Women's Hospital, Boston, Massachusetts; Assistant Professor of Psychiatry, Harvard Medical School, Boston, Massachusetts; Ira Marion, MA (Co-Chair), Executive Director, Division of Substance Abuse, Albert Einstein College of Medicine, Bronx, New York; Mark W. Parrino, MPA (Co-Chair), President, American Association for the Treatment of Opioid Dependence, New York, New York; George E. Woody, MD (Co-Chair), Treatment Research Institute, University of Pennsylvania/MIRECC Philadelphia VAMC, Philadelphia, Pennsylvania; Patrick Abbott, MD, Medical Director, Center on Alcoholism, Substance Abuse, and Addictions, University of New Mexico, Albuquerque, New Mexico; Leslie Amass, PhD, Principal Investigator, Friends Research Institute, Inc., Los Angeles, California; Hector D. Barreto, MD, MPH, Medical Director, Center for Drug-Free Living, Orlando, Florida; Michael D. Couty, Director, Division of Alcohol and Drug Abuse, Missouri Department of Mental Health, Jefferson City, Missouri; Vashti Jude Forbes, RN, BC, MSN, LCDC, Associate Director, Substance Abuse and Specialized Services, Austin Travis County Mental Health and Mental Retardation Center, Austin, Texas; Ron Jackson, MSW, Executive Director, Evergreen Treatment Services, Seattle, Washington; Karol A. Kaltenbach, PhD, Director, Maternal Addiction Treatment Education and Research, Jefferson Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania; Judith Martin, MD, FASAM, Medical Director, 14th Street Clinic & Medical Group, Inc., Oakland, California; Violanda T. Nunez, MSW, Executive Director, Ayudantes, Inc., Santa Fe, New Mexico; J. Thomas Payte, MD, Medical Director, Drug Dependence Associates, San Antonio, Texas; Norma J. Reppucci, RN, Director, Operations for Eastern MA and NH, Community Substance Abuse Centers, Malden, Massachusetts; Yong S. Song, PhD, Assistant Clinical Professor and Program, Director, Opiate Treatment Outpatient Program, University of California, San Francisco, San Francisco, California; Jo L. Sotheran, PhD, Associate Research Scientist, Mailman School of Public Health, Columbia University, New York, New York; Trusandra Taylor, MD, Physician Advisor, Parkside Recovery Methadone Maintenance, Philadelphia, Pennsylvania

Editorial Advisory Board: John D. Crowley, Crowley Associates, Elgin, South Carolina; Herbert D. Kleber, MD, Professor of Psychiatry, Columbia University College of Physicians & Surgeons, New York, New York; Stewart B. Leavitt, PhD, Leavitt Medical Communications, Glenview, Illinois; Jocelyn Sue Woods, MA, President, National Alliance of Methadone Advocates, New York, New York; Joan Zweben, PhD, Executive Director, 14th Street Clinic & Medical Group, Inc., East Bay Community Recovery Project, Berkeley, California

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [National Library of Medicine Health Services/Technology Assessment \(HSTAT\) Web site](#). Also available in Portable Document Format (PDF) from [SAMHSA's National Clearinghouse for Alcohol and Drug Information \(NCADI\) Web site](#).

Print copies: Available from the National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20852. Publications may be ordered from [NCADI's Web site](#) or by calling (800) 729-6686 (United States only).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Executive summary. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. xvii-xx. (Treatment improvement protocol (TIP); no. 43).
- Introduction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 1-10. (Treatment improvement protocol (TIP); no. 43).
- History of medication-assisted treatment for opioid addiction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 11-23. (Treatment improvement protocol (TIP); no. 43).
- Pharmacology of medications used to treat opioid addiction. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 25-42. (Treatment improvement protocol (TIP); no. 43).
- Administrative considerations. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 225-240. (Treatment improvement protocol (TIP); no. 43).
- Appendix D: Ethical considerations in MAT. Medication-assisted treatment for opioid addiction in opioid treatment programs. p. 297-304. (Treatment improvement protocol (TIP); no. 43).

Electronic copies: Available from the [National Library of Medicine Health Services/Technology Assessment \(HSTAT\) Web site](#). Also available in Portable Document Format (PDF) from [SAMHSA's National Clearinghouse for Alcohol and Drug Information \(NCADI\) Web site](#).

The following are also available:

- Knowledge Application Program. KAP keys for clinicians. Based on TIP 43: Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. 20 p. Electronic copies: Available in Portable Document Format (PDF) from the [SAMHSA Web site](#).
- Quick guide for clinicians. Based on TIP 43: Medication-assisted treatment for opioid addiction in opioid treatment programs. Rockville (MD): Substance Abuse and Mental Health Services Administration (SAMHSA); 2005. 39 p.

Electronic copies: Available in Portable Document Format (PDF) from the [SAMHSA Web site](#).

Additionally, sample guidelines for monitoring urine drug test specimen collection can be found in the [original guideline document](#).

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on December 23, 2005. The information was verified by the guideline developer on January 23, 2006.

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